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10/551,262	09/28/2005	Richard Markoll	26993U	3360
20529	7590	09/19/2008	EXAMINER	
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			CHEN, VICTORIA W	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,262	Applicant(s) MARKOLL, RICHARD
	Examiner VICTORIA W. CHEN	Art Unit 3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 August 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 9/28/06 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/0256/06)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6-8 and 12-18 rejected under 35 U.S.C. 103(a) as being unpatentable over Ostrow et al. (US 6443883 B1) in view of Aoki et al. (6464986 B1).

Regarding claim 1, Ostrow teaches a method for treatment of osteoporosis comprising exposing a patient to electromagnetic signals generated by pulsating, impulse modulated direct current, where the frequency is 1 to 30 Hz and the field strength is 1 to 20 G [col. 18, ll. 16-18, 29-31]. However, Ostrow fails to teach the use of Botulinum toxin as an adjuvant to the exposure of the patient to the electromagnetic signals. Aoki teaches the use of Botulinum toxin for the treatment of pain caused by osteoporosis [col. 24, ll. 15-30]. “When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show it was obvious under 35 U.S.C. 103.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to try administering

Botulinum toxin as an adjuvant to the exposure to the electromagnetic signals for the treatment of osteoporosis since both treatments are known to be effective towards treating osteoporosis.

Regarding claim 2, Ostrow teaches the modulation form is quasi-rectangular [col. 18, ln. 16].

Regarding claim 6, Ostrow teaches the pulses are modulated [col. 13, ll. 55-58].

Regarding claim 7, Ostrow teaches a method for administering treatment for osteoporosis comprising exposing a patient to electromagnetic signals generated by pulsating, impulse modulated direct current, where the frequency is 1 to 30 Hz and the field strength is 1 to 20 G [col. 18, ll. 16-18, 29-31]. However, Ostrow fails to teach administering Botulinum toxin as an adjuvant to the exposure of the patient to the electromagnetic signals. Aoki teaches the use of Botulinum toxin intramuscularly for the treatment of pain caused by osteoporosis [col. 24, ll. 15-30]. “When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show it was obvious under 35 U.S.C. 103.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to try administering Botulinum toxin as an adjuvant to the exposure to the electromagnetic signals for the treatment of osteoporosis since both treatments are known to be effective towards treating osteoporosis.

Regarding claims 8 and 12, see rejections of claims 2 and 6 above.

Regarding claims 13, 14, 16 and 17, Aoki teaches the use of 50-200U of Botulinum toxin Type A for treatment of pain [col. 24, ll. 20-22].

Regarding claims 15 and 18, Aoki teaches the use of 50-400U of Botulinum toxin Type B [col. 9, ll. 47-48].

Claims 1, 3, 6, 7, 9 and 12-18 rejected under 35 U.S.C. 103(a) as being unpatentable over Becker et al. (USPGPUB 2004/0077921 A1) in view of Aoki et al. (6464986 B1).

Regarding claim 1, Becker teaches a method for treatment of osteoporosis comprising exposing a patient to electromagnetic signals generated by pulsating, impulse modulated direct current, where the frequency is 1 to 30 Hz and the field strength is 1 to 20 G [see claim 1]. However, Becker fails to teach the use of Botulinum toxin as an adjuvant to the exposure of the patient to the electromagnetic signals. Aoki teaches the use of Botulinum toxin for the treatment of pain caused by osteoporosis [col. 24, ll. 15-30]. “When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show it was obvious under 35 U.S.C. 103.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to try administering Botulinum toxin as an adjuvant to the exposure to the electromagnetic signals for the treatment of osteoporosis since both treatments are known to be effective towards treating osteoporosis.

Regarding claim 3, Becker teaches the frequency is approximately between 5-15 Hz [see claim 3].

Regarding claim 6, Becker teaches that the pulses are modulated [see claim 8].

Regarding claim 7, Becker teaches a method for administering treatment for osteoporosis comprising exposing a patient to electromagnetic signals generated by pulsating, impulse modulated direct current, where the frequency is 1 to 30 Hz and the field strength is 1 to 20 G [see claim 1]. However, Becker fails to teach administering Botulinum toxin as an adjuvant to the exposure of the patient to the electromagnetic signals. Aoki teaches the use of Botulinum toxin intramuscularly for the treatment of pain caused by osteoporosis [col. 24, ll. 15-30]. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show it was obvious under 35 U.S.C. 103." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to try administering Botulinum toxin as an adjuvant to the exposure to the electromagnetic signals for the treatment of osteoporosis since both treatments are known to be effective towards treating osteoporosis.

Regarding claims 9 and 12, see rejections of claims 3 and 6 above.

Regarding claims 13, 14, 16 and 17, Aoki teaches the use of 50-200U of Botulinum toxin Type A for treatment of pain [col. 24, ll. 20-22].

Regarding claims 15 and 18, Aoki teaches the use of 50-400U of Botulinum toxin Type B [col. 9, ll. 47-48].

Claims 1-5, 7-11, 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waltonen et al. (US Pat No 4674482) in view of Aoki et al. (US Pat No 6464986 B1).

Regarding claim 1, Waltonen teaches a method for treatment of osteoporosis comprising exposing a patient to electromagnetic signals generated by pulsating, impulse modulated direct current with a range of frequency and field strength, however does not specifically disclose the range of between 1-30 Hz and 1-20 G. Waltonen does teach a range of frequencies between 1-100 Hz [col. 3, ll. 36-40] and a range of field strength between 4-22 G [col. 3, ll. 56-57]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to find the best set of parameters within those ranges for the treatment of tissue, specifically osteoporosis, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Waltonen fails to teach the use of Botulinum toxin as an adjuvant to the exposure of the patient to the electromagnetic signals. Aoki teaches the use of Botulinum toxin for the treatment of pain caused by osteoporosis [col. 24, ll. 15-30]. “When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show it was obvious under 35 U.S.C. 103.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007). Therefore, it would have

been obvious to one of ordinary skill in the art at the time of invention to try administering Botulinum toxin as an adjuvant to the exposure to the electromagnetic signals for the treatment of osteoporosis since both treatments are known to be effective towards treating osteoporosis.

Regarding claim 2, Waltonen teaches the modulation form is quasirectangular [col. 5, ll. 11-15].

Regarding claims 3-5, see rejection of claim 1 under Waltonen.

Regarding claim 7, Waltonen teaches a method for administering treatment for osteoporosis comprising exposing a patient to electromagnetic signals generated by pulsating, impulse modulated direct current with a range of frequency and field strength, however does not specifically disclose the range of between 1-30 Hz and 1-20 G. Waltonen does teach a range of frequencies between 1-100 Hz [col. 3, ll. 36-40] and a range of field strength between 4-22 G [col. 3, ll. 56-57]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to find the best set of parameters within those ranges for the treatment of tissue, specifically osteoporosis, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Waltonen fails to teach administering Botulinum toxin as an adjuvant to the exposure of the patient to the electromagnetic signals. Aoki teaches the use of Botulinum toxin intramuscularly for the treatment of pain caused by osteoporosis [col. 24, ll. 15-30]. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. In that instance

the fact that a combination was obvious to try might show it was obvious under 35 U.S.C. 103.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to try administering Botulinum toxin as an adjuvant to the exposure to the electromagnetic signals for the treatment of osteoporosis since both treatments are known to be effective towards treating osteoporosis.

Regarding claims 8-11, see rejections of claims 2-5 under Waltonen above.

Regarding claims 13, 14, 16 and 17, Aoki teaches the use of 50-200U of Botulinum toxin Type A for treatment of pain [col. 24, ll. 20-22].

Regarding claims 15 and 18, Aoki teaches the use of 50-400U of Botulinum toxin Type B [col. 9, ll. 47-48].

Response to Arguments

Applicant's arguments filed 8/18/08 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., treating the causes of osteoporosis and not the symptoms) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The synergistic interaction claimed by applicant is considered an "intended use" limitation, which is not given patentable weight. Furthermore, Applicant has not provided sufficient evidence for why the references used above would not be obvious to try, or why the

combination of the references above would not result in the invention as claimed. The MPEP states:

"However, a greater than additive effect is not necessarily sufficient to overcome a prima facie case of obviousness because such an effect can either be expected or unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. *Ex parte The NutraSweet Co.*, 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991)." [MPEP 716.02(a)].

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA W. CHEN whose telephone number is (571)272-3356. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/Victoria W Chen/
Examiner, Art Unit 3739